

3509. Adulteration of diphenylhydantoin sodium capsules. U. S. v. 1 Can
* * *. (F. D. C. No. 30939. Sample No. 5164-L.)

LIBEL FILED: On or about May 3, 1951, District of Rhode Island.

ALLEGED SHIPMENT: On or about March 2, 1951, by the Richlyn Laboratories, from Philadelphia, Pa.

PRODUCT: 1 can containing 18,000 capsules of *diphenylhydantoin sodium* at Howard, R. I.

LABEL, IN PART: "Diphenyl Hydantoin Sodium 1½ Grains."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Diphenylhydantoin Sodium Capsules," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in such compendium. The compendium provides that diphenylhydantoin sodium capsules contain not less than 93 percent of the labeled amount of diphenylhydantoin sodium, whereas the article contained not more than 86 percent of the labeled amount of diphenylhydantoin sodium.

DISPOSITION: June 21, 1951. Default decree of condemnation and destruction.

3510. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle
* * *. (F. D. C. No. 31315. Sample No. 24522-L.)

LIBEL FILED: July 3, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about December 21, 1950, from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle of *conjugated estrogens* at Bayonne, N. J. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.66 mg. of sodium estrone sulfate per tablet.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained in each tablet less than the stated amount of the total estrogenic steroids calculated as sodium estrone sulfate.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: August 14, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Federal Security Agency.

3511. Adulteration and misbranding of Cogenat tablets (conjugated estrogens). U. S. v. 195 Bottles, etc. (F. D. C. No. 31231. Sample Nos. 1831-L, 1832-L.)

LIBEL FILED: On or about July 5, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about June 30 and July 8 and 19, 1949, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: *Cogenat tablets* (conjugated estrogens). 195 100-tablet bottles, 1 1,000-tablet bottle, and 19 100-tablet bottles at Atlanta, Ga.

Analysis showed that the 195-bottle lot contained a total amount of estrogenic steroids calculated as not more than 0.38 mg. of sodium estrone sulfate per tablet, and that the 1-bottle and the 19-bottle lots contained a total amount

of estrogenic steroids calculated as not more than 0.55 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: (195-bottle lot) "Cogenat 0.625 mg. Conjugated Estrogens" and (1-bottle and 19-bottle lots) "Cogenat 1.25 mg. Conjugated Estrogens."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article in each of the two lots differed from that which it was represented to possess, namely, 0.625 mg. and 1.25 mg., respectively, of conjugated estrogens expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statements on the two lots of the article, namely, "Each tablet contains: Conjugated Estrogens * * * 0.625 mg. [or "1.25 mg."] expressed as Sodium Estrone Sulfate" were false and misleading as applied to an article containing less than the stated amounts of estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3512. Adulteration and misbranding of Conjugens tablets and Conjugestoral tablets (conjugated estrogens). U. S. v. 2 Bottles, etc. (and 1 other seizure action). (F. D. C. Nos. 30767, 39872. Sample Nos. 23103-L, 23105-L.)

LIBELS FILED: March 8 and 27, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about November 20 and 22 and December 4, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 2 1,000-tablet bottles and 1 bottle containing 600 tablets of *Conjugens* and 1 1,000-tablet bottle of *Conjugestoral* at East Orange, N. J., and 1 bottle containing approximately 350 *Conjugens* tablets at Bloomfield, N. J.

Analyses of two samples taken from the shipments of *Conjugens* showed the total amount of estrogens actually present in the samples to be equivalent to 0.56 mg. and 0.78 mg., respectively, of sodium estrone sulfate per tablet. Analysis of a sample of the *Conjugestoral* tablets showed the total amount of estrogens actually present in the sample to be equivalent to 0.35 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Tablets Conjugens (Conjugated Estrogens) * * * Distributed by Success Chemical Co., Inc., Brooklyn, New York" and "Tablets Conjugestoral (Conjugated Estrogens) * * * Distributors Corby-Franklin Associates New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the articles, which contained less than the stated amount of estrogens.

DISPOSITION: July 11 and 12, 1951. Default decrees of condemnation. The court ordered that the lot seized at Bloomfield be destroyed and that the lots seized at East Orange be delivered to the Food and Drug Administration.

3513. Adulteration and misbranding of Estrotron. U. S. v. 40 Bottles * * *. (F. D. C. No. 30930. Sample No. 29728-L.)

LIBEL FILED: April 24, 1951, Western District of Washington.